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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/293,835 | 04/19/1999 | JAMES C. KENNEDY | 067286/136/D | 5426 |

7590

04/23/2003

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WASHINGTON, DC 20007

| EXAMINER |
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SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 04/23/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/293,835

Applicant(s)

KENNEDY ET AL

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 18, 19, 24, 27-39, 41, 47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 18, 19, 24, 27-39, 41, 47 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for reconsideration filed on December 11, 2002 has been entered.

Claims 1, 15, 18-19, 24, 27-39, 41-47, 49-51 are pending. Applicant has elected such species directed to fungus as the exogenous origin, skin as the tissue, onychomycosis as the disorder, and 5-aminolevulinic acid as the precursor of protoporphyrin IX in Paper No. 10. Examination of the claims are continued to the extent that it reads on the elected species.

Priority

The effective priority date of the pending claims is considered to be the filing date of parent application 08/465,242 which is June 5, 1995 for the reasons set forth in the Office Action filed on June 12, 2000, Paper No. 8.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 15, 18-19, 24, 27-39, 41-47, 49-51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al US Patent 5,705,518 in view of Levy et al US Patent 5,283,255.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive for the previously elaborated reasons of record.

Applicant first argues that Richter discloses that papilloma virus is effectively treated with 5-ALA because the drug targets "area of neovascularization." Applicant then asserts Fungi do not have vessels, thus fungi can not be treated because it is not

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an area of neovascularization. (see Amendment at page 3). As discussed in previous Office Action Paper No. 20, this conclusion is scientifically incorrect. Creation of the area of neovascularization" is an endogenous immunologic reaction towards infection, regardless of its pathogen. Therefore, at the presence of a systemic infection, the ordinary skill in the art would expect "area of neovascularization." Applicant then asserts Fungi do not have vessels thus, can not be treated with this methodology. Moreover,⁷⁾ Attention is drawn to Stryer Biochemistry, Chapter 34, pages 851-856. Accordingly, Like Fungi, viruses don not have vessels, therefore, applicant's reasoning is flawed.

Moreover, Levy specifically teaches the use of his methodology for treating infectious agents, in vivo or ex vivo, including fungal or viral pathogens (col 19, lines 9-25). Therefore, Levy only differs from the instant claims by using a different therapeutic agent, such as hydromoo benzoporphyrins. Richter provides this lack of teaching. It is worth mentioning that Hydromonobenzoprohyrins provides the same function in vivo as 5-Ala, therefore, substituting 5-Ala for the agents used by Levy would have been obvious.

Applicant's assertion about the cellular mechanism of phylogenetic continuum is noted but is not persuasive, because Levy provides for treating fungi or parasitic infection by employing photodynamic therapy.

Applicant's arguments that Levy fails to show effective treatment of onychomycosis is noted, but are not found persuasive, because they are not commensurate with the scope of the pending claims. none of generic claims are directed to method of treating onychomycosis. Nevertheless, Levy specifically indicates

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that such photodynamic treatment can be used to treat athlete's foot (see col 19, line 4).

It is well known in the art that athlete's foot is caused by tinea pedis which leads to similar pathophysiological conditions such as onychomycosis.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
April 21, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200